

Summary of Safety and Effectiveness Information

FEB 14 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR 807.92.

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Date of Preparation: 01/27/97

Name of Product: MMB Method for the Dimension® RxL Clinical Chemistry System

FDA Classification Name: Creatine Kinase or Isoenzyme Test System

Predicate Device: Abbott Laboratories IMx® Stat CK-MB

Device Description: The MMB Method for the Dimension® RxL Clinical Chemistry System is a one-step enzyme immunoassay based on the "sandwich" principle. Sample is incubated with chromium dioxide particles, coated with monoclonal antibodies specific for the CKB subunit, and conjugate reagent (β -galactosidase labeled monoclonal antibodies specific for CKMB isoenzyme). A particle-CKMB-conjugate sandwich forms during the incubation period. Unbound conjugate and analyte are removed by magnetic separation and washing. The sandwich bound β -galactosidase is combined with a chromogenic substrate chlorophenyl red- β -d-galactopyranoside (CPRG). Hydrolysis of CPRG releases a chromophore (CPR). The color change at 577 nm is directly proportional to the concentration of CKMB in the original sample.

Intended Use: The MMB Method for the Dimension® RxL Clinical Chemistry System with the heterogeneous immunoassay module is used to quantitatively measure CKMB in human serum and plasma.

**Comparison to Predicate
Device:**

<u>Item</u>	<u>Dimension® RxL MMB</u>	<u>Imx® Stat CK-MB</u>
Technology	Sandwich format monoclonal antibody immunoassay	Sandwich format monoclonal antibody immunoassay
Detection	Colorimetric rate measurement at 577nm and 700nm	Fluorometric endpoint measurement

Comments on Substantial

Equivalence: Split sample comparison between the MMB Method for the Dimension® RxL clinical chemistry system and the Abbott IMx® Stat CK-MB assay gave a correlation coefficient of 0.998, slope of 0.845, and an intercept of 0.496 ng/mL when tested with 137 clinical patient samples ranging from 0.2 - 283.4 ng/mL.

Conclusion: The MMB Method for the Dimension® RxL clinical chemistry system is substantially equivalent in principle and performance to the Abbott IMx® Stat CK-MB Assay based on the split sample comparison discussed above.



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Date: 01/27/97